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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	4354-110	4322

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
02/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 40-51* is/are pending in the application.

4a) Of the above claim(s) *6-29 and 40-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A Request for Continued Examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2008 has been entered.

Applicants' Amendment filed October 21, 2008 is acknowledged in which amendments to claims 2-5 are noted. Claims 6-29 and 40-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 1-5 and 49-51 remain under consideration wherein the subject matter under consideration is limited to pharmaceutical compositions comprising rifalazil.

Applicants' arguments have been fully considered. Those rejections previously set forth that are not herein reiterated are withdrawn. The following rejections represent the only rejections presently applied.

Claims 1-5 and 49-51 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43-45 of copending Application No. 10/948608. The conflicting claims are not identical, but the claims are not patentably distinct from each other. The claims of the co-pending applications recite pharmaceutical compositions or formulations comprising rifalazil.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 7,220,738 and claim 4 of U.S. Patent 7,271,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patents recite pharmaceutical compositions or formulations comprising rifalazil.

Applicants again choose to hold these issues in abeyance.

In the last Office Action claims 1-3, 5 and 49-51 remained rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences.

Rose teaches single-dose oral administration of compositions comprising rifalazil in an amount at least of 1 mg or 5 mg. See the Abstract and claims 1, 11 and 16 in columns 33- 34. Remington provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosages with a higher amount of active antibiotic in the first dosage unit, as required by instant claim 50. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state. All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to

facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional. It has been held that Applicant is not entitled to patent a known product by simply attaching a set of instructions to that product. See In re Ngai, 367 F.3d 1336,70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

Applicants argue Rose does not teach administering rifalazil in a unit dosage amount of 1 mg. Applicants urge there is no motivation to combine Remington because Rose teaches that a dosing regimen with frequent doses at higher concentrations is necessary to treat tuberculosis. Applicants' arguments are essentially directed to intended uses of the claimed pharmaceutical compositions.

Applicants' arguments are not found persuasive. Intended use confers no patentable weight to composition claims. A pharmaceutical composition must be both new and unobvious to one skilled in the art. *In re Hack*, 114 USPQ 161 (CCPA 1957). A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is entirely conventional. Rose clearly teaches the oral administration of 1 mg of rifalazil in a tablet or capsule formulation.

Remington is properly applied as a secondary reference to show a dosing regimen wherein a higher amount of active antibiotic, i.e., in a loading dose regimen, is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such

loading doses, as taught by Remington, reflects conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

In view of the combined teachings of Rose and Remington, one skilled in the art of formulation chemistry would have been motivated to prepare unit dose packaging of the drug rifalazil in an amount between 1-5 mg/unit. According to Remington, packaging of pharmaceutical agents as unit doses, along with instructions thereto, comprising a loading dose, followed by a second, lower dosage unit, is conventional therapeutic practice.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 30, 2009 /Phyllis G. Spivack/

Primary Examiner, Art Unit 1614